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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/529,925 07/30/00 GEORGES E 641050.90013

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HM22/0504

EXAMINER

| ROBINSON, H | |
|-------------|--------------|
| ART UNIT | PAPER NUMBER |

1653 10
DATE MAILED: 05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/529,925

Applicant(s)

Georges et al.

Examiner

Hope Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 26, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above, claim(s) 1-14 and 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

1. Applicant's election without traverse of Group II in Paper No. 9 is acknowledged.

Oath/Declaration

2. The Oath/Declaration is objected to because it is difficult to read the names of the inventors. A substitute Oath/Declaration which clearly sets forth the inventors' names is required.

Abstract

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-23 are rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 15 is indefinite because the claim recites “affects Annexin-based MDR” which is confusing as the preamble of the claim, because the extent of “affecting” or how the compound is affecting cannot be readily ascertained. The claim is also indefinite as to the mere recitation of the name “MDR”, which is insufficient to convey with clarity that which applicant sees as the invention. It is not clearly delineated how the compound is “affecting” as the claim only recites “Annexin-based MDR-affecting compound. It is also unclear how “a compound” is to be selected. The claim is further indefinite regarding the conditions, it is difficult to determine what “drug” the affecting compound will be incubated with or not according to item (a) of the claim. Claim 15 is also indefinite in that the claim fails to clearly delineate an assay which appears required to identify the Annexin-based MDR-affecting compound. Further, the claim does not set forth a method step to demonstrate how to “assess” the effect of the compound or to demonstrate the end point of the method. The dependent claims are included in this rejection.

Claim 17 is indefinite because the claim recites “small molecule”. This terminology is not specific as to the identity of the material proposed (see also claim 20).

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Claim 18 is vague and indefinite in the recitation of “an antisense”. This terminology is not specific as to the identity of the material proposed (see also claim 22).

Claim 20 is indefinite because the claim recites a “method of modulating Annexin-based MDR in a cell” and does not recite whether modulation is up or down.

Claim Rejections - 35 U.S.C. § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 15 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Biochemical and Biophysical Research Communications, vol. 236, pages 483-488, 1997) based on the disclosure which states that P-40 is Annexin I and that the invention relates to the identification of Annexins (I-XI, also referred to herein as P-40 and P-40 homologs (see page 4 of the specification).

Wang disclose a method that identifies a protein that mediates drug resistance to anticancer drugs. Wang also disclose a method that was used to isolate a monoclonal antibody (IPM96) which recognized a protein (P-40) co-expressed with P-glycoprotein in several resistant cell lines. Wang further discloses that overexpression of P-40 in multidrug resistant cells may be important in the expression of the drug resistance phenotype (see pages 483-485).

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Additionally, Wang disclose a method comprising the binding of IMP96 to P-40 in MCF-7/Adr cells (see Figure 1) and demonstrates that P-40 (Annexin I) confers resistance to Taxol and Adriamycin (see Table 1). Wang further discloses that the overexpression of P-40 in paclitaxel or cis-platinum selected cell lines, in the absence of a detectable level of P-gp or MRP supports the notion that P-40 alone may confer resistance to cytotoxic drugs (see page 486). Wang also disclose that P-40 could modulate an MDR phenotype indirectly, by stating that P-40 may be a component of the apoptosis signaling pathway. Moreover, Wang discloses that changes in the levels or functions of proteins involved in the signaling of apoptosis can confer an MDR phenotype on tumor cells (see page 487).

Therefore, Wang anticipates the claimed invention as Wang identifies a compound (P-40) that affects Annexin-based MDR in a cell in the presence of a drug (Adriamycin and Taxol) and assessed the effect of said compound as claimed in the present application. Further, Wang discloses a method that utilizes an antibody to Annexin and a compound that modulates Annexin based MDR in a cell as the present application discloses that P-40 and Annexin are equivalent.

Art of Record

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Kraus et al. (Journal of Immunoassay, vol. 13, no.3, pages 411-439, 1992. Kraus teach the characteristics of Annexins and their use with autoimmune diseases as well as cancer.

Carson et al. (U.S. Patent No. 6,162,810, December 19, 2000). Carson teach compounds that affect cells which have acquired MDR.

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

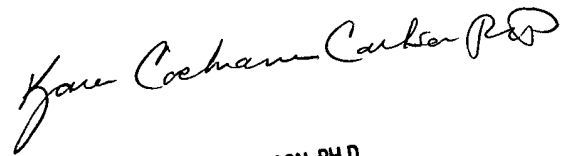
Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response.

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The faxing of such papers must conform with the notice published in the Official Gazette, 1096
OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER